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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/509, 677 03/30/00 II

N 058580

EXAMINER

HM12/0608...

HUT, S

ART UNIT

PAPER NUMBER

3

1617

DATE MAILED:

06/08/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Offic Action Summary</b>	Application No.	Applicant(s)
	09/509,677	II ET AL.
	Examiner San-ming Hui	Art Unit 1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-20 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- |   |  |
|---|--|
| 15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                    | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)           | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 20) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for drug compounds listed in specification from page 6, line 15 to page 8, line 5, does not reasonably provide enablement for any other drug with unpleasant tastes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

There is no adequate direction provided by the applicant as to how to select other drugs with unpleasant tastes which would be suitable in the instant invention.

Furthermore, the instant specification does not provide any working examples to point out how other drugs with unpleasant tastes other than the compounds listed in the specification from page 6, line 15 to page 8, line 5 may be used successfully in the claimed invention.

Moreover, it is well known in the art that structural differences in active compounds will impart different chemical, physical, and therapeutic properties to the same compounds. Therefore different drug compounds with unpleasant tastes, other than the ones listed in specification from page 6, line 15 to page 8, line 5, may be reasonably expected to yield a different result. Due to this unpredictability, it would

prevent the skilled artisan from selecting a compound which may be termed a "drugs with unpleasant taste" to retain the desired function of the instant invention to improve taste in the oral therapeutic preparation with sugar alcohols specified herein, without undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression "unpleasant taste" in claim 1-4,6,9-11, 13-14, and 19 is a relative term which renders the claim indefinite. The expression "unpleasant taste" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear what drugs are encompassed by the claims.

The expression "bitter taste" in claim 2 is a relative term which renders the claim indefinite. The expression "bitter taste" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear as to what drugs are encompassed by the claims.

The term "corrective agent" in claims 16 and 20 renders the claims indefinite as to what agents are encompassed by the claims. This term is not understood.

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The expression "taking ability" in claims 19 and 20 is not understood. It appears that applicants' invention is directed to a method of improving (masking) tastes of an oral preparation. See, e.g., page 1, para. 1 in the specification. An amendment to this effect would be favorably considered.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9, 12-14, 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Pearmain (US Patent 5,188,839).

Pearmain teaches cimetidine tablet, which improve palatability, that contains sodium bicarbonate, sorbitol and a sweetener aspartame (See particularly the abstract, col.4, example 3). Pearmain also teaches the ratio between sorbitol and cimetidine is about 3.5 to 1; the ratio between sodium bicarbonate and cimetidine is about 0.9 to 1 (See particularly col. 4, example 3).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8, 10-11, 15, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pearmain (US Patent 5,188,839) in view of Hoshino (WO 97/12606, English equivalent, US Patent 6,146,661, is also provided).

Pearmain teaches a cimetidine tablet, with improves palatability, that contains sodium bicarbonate, sorbitol and a sweetener aspartame (See abstract, col.4, example 3).

Pearmain does not expressly teach that erythritol, the sugar alcohol, is in the cimetidine tablet. Pearmain does not expressly teach that the ratio between the sugar alcohol to cimetidine is from 5 to 10 : 1. Pearmain does not expressly teach that the pH values of the solution of the pH adjusting agent be equal to or higher than that of the solution of cimetidine. Pearmain does not expressly teach a method of improving "taking ability" employing the cimetidine tablet with improved palatability.

Hoshino teaches a chewable tablet that is free from unpleasant intrabuccal (oral) sensation which may contain a H<sub>2</sub> receptor blocking agent including cimetidine and erythritol (See abstract, claim 1). Hoshino also teaches a method of improving the unpleasant taste of the tablet with sugar alcohol herein, including erythritol (See col. 1, lines 51-58; col. 2, lines 25-56 particularly, and col. 6, line 1 to 60).

It would have been obvious for one of ordinary skill in the art at the time the invention was made to employ the sugar alcohol, erythritol in the cimetidine tablet of Pearmain, with the ratio between the sugar alcohol to cimetidine being from 5 to 10 : 1

and the pH values of the solution of the pH adjusting agent be equal to or higher than that of the solution of cimetidine.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to employ the cimetidine tablet in a method of improving "taking ability".

One of ordinary skill in the art would have been motivated to incorporate erythritol into the cimetidine tablet of Pearmain because it is known in the art that erythritol is useful to improve from unpleasant intrabuccal (oral) sensation in chewable tablet compositions. The incorporation of erythritol to improve the taste of a cimetidine tablet is therefore *prima facie* obvious.

Optimization of result effect parameters (i.e., ingredient amounts, solutions, or suspension, pH values) is obvious as being within the skill of the artisan.

One of ordinary skill in the art would have been motivated to employ the cimetidine tablet of Pearmain as modified by Hoshino in a method of improving taking ability because the tablet would be expected to have improved taste and oral sensation and therefore the tablet would have been reasonably expected to be more pleasant to "take" or ingest orally.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Monday to Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone

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numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui  
June 4, 2001

*Minna Moez*  
MINNA MOEZIE, J.D.  
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